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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/736,267 10/24/96 BACKSTROM

K 06275/004001

EXAMINER

18M1/0718

ART UNIT 14, PAPER NUMBER

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1817

DATE MAILED: 07/18/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/5/97 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-22 and 26-60 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-22 and 26-60 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Status of Claims

1. This is a file wrapper continuation of application No. 08/265237. Claims 1-22 and 26-60 are pending in this Office action. Claims 23-25 have been canceled.
2. The amendment filed November 8, 1995 requests replacement of Table I with the substitute page "Exhibit A". No Exhibit A was included with the papers as entered. However, the spelling of "Didecanoylphosphatidylcholine" at line 10 of Table I has been corrected. Any further changes to the table should be made by an additional amendment or replacement Table I.

Response to Amendment

3. The rejection of claims 2, 4, 12 and 27 under 35 U.S.C. § 112, second paragraph is withdrawn with respect to claim 2 due to amendment to the claim, and maintained with respect to claims 4, 12, and 27 for the reasons cited in the previous Office action. Applicant's arguments filed November 8, 1995 have been fully considered but they are not deemed to be persuasive. The term "analogue" fails to impart reasonable limits upon what is being claimed because this term is by nature nebulous. Analogues of vasopressin, for example, are not limited in any way to a certain percentage of sequence homology or even size in comparison to vasopressin. Moreover, the addition of the term "polypeptide" by applicant fails to further limit the meaning of the term, or to define a single class of molecules, because the term "analogue" is subject to various interpretations by those of ordinary skill in the art. A similar line of reasoning applies to the use of the term "derivative" by applicant, since it is unclear what this term is meant to suggest. Contrary to applicant's assertions, the term "derivative" is not recognized in the art as being limited to compounds in which various counterions are used, or to esterified forms, and is not further defined with respect to bile salts at page 4 of the specification. Indeed, a derivative could be considered to be any chemically related species. If applicant wishes to claim the specific forms of derivative outlined in the amendment they should be explicitly stated in the

claim language (assuming, of course, adequate support in the specification). Thus these terms are unclear and confusing, and fail to satisfy the strictures of the statute.

4. The rejection of claims 1-14, 17-22, and 26-29 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Platz et al. [U.S. Patent No. 5,284,656] is maintained for the reasons cited in the previous Office action and extended to include new claims 33-60. Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The pharmaceutical compositions of Platz et al. contain a pharmaceutically active dry powder polypeptide and an absorption enhancer for administration via a dry powder inhaler device which meet the specific limitations of applicant's claims, and therefore are considered identical to those disclosed by applicants. At column 4 lines 6-17, for example, Platz discloses a dry powder polypeptide (G-CSF) in the presence of a propellant "with the aid of a surfactant". The propellant does not, of course, change the fact that the preparation is a dry powder, and Platz suggests the use of a fatty acid such as oleic acid or sorbitan trioleate as a surfactant. It would have been clear to the artisan at the time the invention was made that use of a surfactant in the Platz preparations renders the surfactant a *de facto* absorption enhancer since the intent was to maximize absorption of the polypeptide. Moreover, at page 10 lines 21-32 of the specification applicants suggest the use of fatty acid salts as absorption enhancers. Therefore the preparations of Platz do indeed meet the limitations of applicant's claims, or would render these claims obvious due to the specific types of embodiment disclosed by Platz.

5. The rejection of claims 1-3, 5-11, 17, 18, 21, 22, 26, and 28-32 under 35 U.S.C. § 103 as being unpatentable over Rubsamen [U.S. Patent No. 5,364,838] in view of Platz et al. [U.S. Patent No. 5,284,656] is maintained for the reasons cited in the previous Office action and extended to include new claims 33-60. Rubsamen at column 15 lines 31-34 discloses a formulation containing insulin, a propellant, and oleic acid. As discussed above, the oleic acid

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would be recognized by the artisan as having the effect of increasing insulin absorption, and therefore would function as an enhancer. In view of the Platz reference teaching the required particle size this combination of references renders applicant's invention obvious.

6. The rejection of claims 1, 2, 6-18, 21, 22, and 28-32 under 35 U.S.C. § 103 as being unpatentable over Rubsamen [U.S. Patent No. 5,364,838] in view of Clark et al. [U.S. Patent No. 5,341,800] and further in view of Edman et al. [Advanced Drug Delivery Reviews 8, 165-177 (1992)] and Mishima et al. [J. Pharmacol.-Dyn. 10, 624-631(1987)] is maintained for the reasons cited in the previous Office action and extended to include new claims 33-60. Rubsaman and Platz are discussed above.

7. The provisional rejection of claims 1, 2, and 6-19 over 08/265372 is withdrawn in view of applicant's arguments.

General information regarding further correspondence


The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benet Prickril, Ph.D., whose telephone number is (703) 305-5933. The examiner normally can be reached Monday through Thursday between 7:30 AM and 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached at (703)308-4310. The fax phone number for Art Unit 1817 is (703) 305-7939.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Benet Prickril, Ph.D.
July 3, 1997


PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER
GROUP 1800